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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,199	09/09/2003	Chin-Chu Chen	MR2723-307	9131

4586 7590 01/10/2007  
ROSENBERG, KLEIN & LEE  
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ELLICOTT CITY, MD 21043

EXAMINER
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HANLEY, SUSAN MARIE

ART UNIT	PAPER NUMBER
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1651

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/10/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

**Application No.**

10/657,199

**Applicant(s)**

CHEN ET AL.

**Examiner**

Susan Hanley

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 13 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-4 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 October 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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#### DETAILED ACTION

The amendment and remarks filed 10/13/06 are acknowledged.

Claims 1-4 remain under examination.

#### *Oath/Declaration*

The declaration filed 10/13/06 by Ying-Shih Feng regarding the name of Inventor Paul Feng is acceptable and overcomes the objection to the Oath/Declaration.

#### *Drawings*

The drawing was received on 10/13/06. The drawing is acceptable.

#### *Claim Rejections - 35 USC § 112*

Claims 1-4 stand rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of producing the beta-lactam antibiotics consisting of the structural formula of the compounds of Figures 8, 12 and 14, from a protoplast fusion strain CCRC 930060 which is obtained by fusing protoplasts of *Penicillium chrysogenum* (ATCC 48271) and *Cephalosporium acremonium* (CCRC 31697), does not reasonably provide enablement for a method of producing any possible beta-lactam antibiotic in accordance with Figure 8, 12 and 14 from a protoplast fusion strain CCRC 930060 which is obtained by fusing the protoplasts of *Penicillium chrysogenum* (ATCC 48271) and *Cephalosporium acremonium* (CCRC 31697). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

The claims have been amended to recite a method of producing any possible beta-lactam antibiotics in accordance with Figure 8, 12 and 14 from a protoplast fusion strain CCRC 930060 which is obtained by fusing the protoplasts of *Penicillium chrysogenum* (ATCC 48271) and *Cephalosporium*

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*acremonium* (CCRC 31697). The claims stand rejected because the language "...in accordance with Figure 8, 12 and 14 from a protoplast fusion strain CCRC 930060 ..." continues to read beyond the scope for which the invention is enabled with regard to the compounds that are made by the protoplast fusion strain. The transitional phrase "in accordance with," in the absence of evidence to the contrary, is considered to mean "in agreement with." This is considered to be "open" claim language because the phrase is subjective. That is, "to be in agreement with" does not necessarily define what something is. Two people may be in agreement about an object or an issue, but such "agreement" does not define exactly what the true nature of the object or issue is. Thus, there is room for interpretation as to the structures of the compounds encompassed by the amended claim language. The specification supports that one of skill in the art can obtain the fusion strain CRC 930060 from the protoplast fusion of microorganisms belonging to the strains *Penicillium chrysogenum* (ATCC 48271) and *Cephalosporium acremonium* (CCRC 31697) to obtain beta-lactam antibiotics consisting of the structural formula of the compounds of Figures 8, 12 and 14. The limited showing of the production of three antibiotics from a novel fusion protoplast with a particular activity is not sufficient to enable a claim drawn to a method for producing any possible beta-lactam antibiotic from a protoplast fusion strain CCRC 930060 obtained from the combination of microorganisms belonging to the strains *Penicillium chrysogenum* (ATCC 48271) and *Cephalosporium acremonium* (CCRC 31697) because the art of microbiology is complex and unpredictable.

The specification does not disclose if one skilled in the art can utilize the claimed protoplast fusion strain of *Penicillium chrysogenum* and *Cephalosporium acremonium* to synthesize any possible beta-lactam antibiotic with a reasonable expectation of results. The specification and the prior art disclose that the method of obtaining a fusion protoplast from the combination of *Penicillium chrysogenum* and *Cephalosporium acremonium* to produce beta-lactam antibiotics is rare and an individual characteristic of said strains. Furthermore, a search of the Registry database showed that compounds 3-3-A-2 and M-4 are novel compounds, while A-3-2 has only been reported nine times in the literature. Neither *Penicillium chrysogenum* (ATCC 48271) nor *Cephalosporium acremonium* (CCRC 31697) have been reported to make any

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other claimed compounds individually. Hence, one skilled in the art would be unable to predict the structures of other possible beta-lactam compounds that the novel protoplast fusion strain may produce based on the instant disclosure. If the method of claim 1 is not generally applicable to any possible beta-lactam, then the structures of all possible known and unknown beta-lactams would be considered individually. This would be considered undue experimentation.

There is no reliable method that predicts the structures of beta-lactam antibiotics produced by the claimed fusion strain, other than the beta lactams consisting of the structural formula of the compounds of Figures 8, 12 and 14. Applicants acknowledge the difficulty in fusing *Penicillium chrysogenum* and *Cephalosporium acremonium* to make a viable protoplast that makes certain beta-lactam antibiotics. The specification does not teach how one of ordinary skill in the art could decide *a priori* what the structures of other possible beta-lactam compounds might be produced by the fusion strain. The limited disclosure cannot be extrapolated by the skilled artisan to predict what other than the beta lactams consisting of the structural formula of the compounds of Figures 8, 12 and 14 are produced by the claimed protoplast fusion strain. It would require one of ordinary skill in the art undue experimentation to determine what other than the beta lactams consisting of the structural formula of the compounds of Figures 8, 12 and 14 are produced by the claimed protoplast fusion strain according to the directions of the instant disclosure. Thus, claims 1-4 are still not commensurate in scope with the enabling disclosure.

Claims 1-4 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, the claims encompass the production of a multitude of possible beta lactam antibiotics for which only three structures have been supplied in the as-filed disclosure. The claims are drawn to a method of producing any possible beta-lactam antibiotics in accordance with Figure 8, 12 and 14 from a protoplast fusion

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strain CCRC 930060 which is obtained by fusing the protoplasts of *Penicillium chrysogenum* (ATCC 48271) and *Cephalosporium acremonium* (CCRC 31697). The claims stand rejected because the language "...in accordance with Figure 8, 12 and 14 from a protoplast fusion strain CCRC 930060 ..." continues to read beyond the enabled scope of the invention with regard to the compounds that are made by the protoplast fusion strain. The transitional phrase "in accordance with," in the absence of evidence to the contrary, is considered to mean "in agreement with." This is considered to be "open" claim language because the phrase is subjective. That is, "to be in agreement with" does not necessarily define what something is. Two people may be in agreement about an object or an issue but such "agreement" does not define exactly what the true nature of the object or issue is. Thus, there is room for interpretation as to the structures of the compounds encompassed by the amended claim language. However, the specification supports that one of skill in the art can obtain the fusion strain CRC 930060 from the fusion of protoplast obtained from the strains, *Penicillium chrysogenum* (ATCC 48271) and *Cephalosporium acremonium* (CCRC 31697), to yield beta-lactam antibiotics consisting of the structural formula of the compounds of Figures 8, 12 and 14. The limited scope of the examples provided in the specification as filed clearly does not provide a representative sample of beta-lactam compounds encompassed by the claims, given the huge variation in physical, structural, and chemical properties encompassed by the current broad claim language. Because the claims encompass a multitude of products neither contemplated nor disclosed by the as-filed disclosure, it is clear that applicant was not in possession of the full scope of the claimed subject matter at the time of filing.

The declaration filed 10/13/06 by Shui-Chao Tseng regarding the availability of the deposited regarding the deposit of the fusion strain CCRC930060 is sufficient to overcome the rejection based on 35 USC 112, first paragraph.

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Claim1-4 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected because it is unclear if the protoplast fusion strain (CCRC930060) recited in the preamble is the same protoplast fusion strain resulting from the culturing of *Penicillium chrysogenum* (ATCC 48271) nor *Cephalosporium acremonium* (CCRC 31697) that is recited in the body of the claim.

Claim 1 is rejected because step (e) which recites "analyzing the product of step (f)" is confusing because there is no step "(f)" that precedes step (e).

Claim 1 recites the limitation "active antibiotics" in steps (e) and (f). There is insufficient antecedent basis for this limitation in the claim.

The term "active" in claim 1 (steps (e), (f) and (g)); claim 2 (line 2 of the claim); claim 3 (last line); and the penultimate line of claim 4 is a relative term which renders the claim indefinite. The term "active" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear what level of activity is required to qualify an antibiotic or substance as "active."

Claims 3 and 4 are rejected because the phrase "preparation type HPLC" is vague and indefinite. It is unclear what properties qualify an HPLC separation procedure as "preparation type" as compared to a non-preparation-type. It is suggested that the term be changed to "preparative HPLC."

Claims 3 and 4 are rejected because they are confusing when read in light of claim 1. Claim 1 recites a method having steps (a)-(g). Claims 3 and 4 recite additional limitations to obtain a specific beta-lactam antibiotic but is unclear if these additional steps are meant to precede, occur afterward or be interspersed at some particular points within steps (a)-(g) of claim 1.

No claim is allowed.

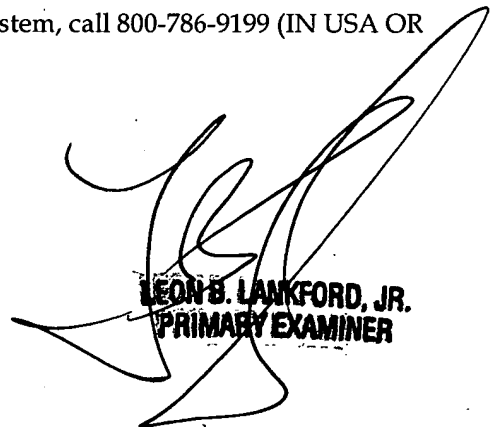
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Hanley whose telephone number is 571-272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Susan Hanley  
Patent Examiner  
1651



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PRIMARY EXAMINER